PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1060/773/PWO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/GB2005/000524	International filing date *(day/month/year)* 15.02.2005	Priority date *(day/month/year)* 19.02.2004
International Patent Classification (IPC) or national classification and IPC INV. A61K7/48		
Applicant BOOTS HEALTHCARE INTERNATIONAL LIMITED et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 1 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.12.2005	19.05.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Menidjel, R Telephone No. +31 70 340-3680

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2005/000524

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-22	as originally filed

Claims, Numbers

1-42	as originally filed
43-48	filed with telefax on 16.12.2005

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 40-44

because:

☒ the said international application, or the said claims Nos. 40-44 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-48
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-48
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-39,45-48
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- The subject-matter of claims 40-44 is related to a method for treatment of the human or animal body from surgery or therapy. Using its discretion, the present authority decided not to carry out an internal preliminary examination on that subject-matter (Article 34(4)(a) PCT in conjunction with Rule 67.1(iv) PCT).

For the assessment of the present claims 40-44 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- The amendments filed by the applicant do not introduce subject-matter which extends beyond the content of the application as filed (Article 34(2)(b) PCT).

1 - The following documents (D1-D4) are referred to in this communication (Article 33(6) PCT); the numbering will be adhered to in the rest of the procedure:

D1: WO 03/022236 A (UNILEVER PLC; UNILEVER NV; HINDUSTAN LEVER LIMITED) 20 March 2003 (2003-03-20)

D2: US-A-5 736 582 (DEVILLEZ ET AL) 7 April 1998 (1998-04-07)

D3: WO 03/022237 A (UNILEVER PLC; UNILEVER NV; HINDUSTAN LEVER LIMITED) 20 March 2003 (2003-03-20)

D4: WO 01/28338 A (THE PROCTER & GAMBLE COMPANY) 26 April 2001 (2001-04-26)

2. Novelty (Article 33(2) PCT)

- The subject-matter of present claims 1-48 is considered as novel over the cited prior art for

the following reasons (Article 33(2) PCT):

- Document D1, cited by the applicant, describes a cosmetic composition comprising salicylic acid or a salt thereof and a gelling agent in the form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof (Cf. D1, page 2, line 25-page 4, line 17; page 6, line 24-line 28; page 7, line 1-line 6; page 12, line 1-line 14).

- Document D2 refers to a composition for treating the skin comprising hydrogen peroxide and salicylic acid as active agents (Cf. D2, column 2, lines 30-49; column 3, lines 7-41; column 4, lines 3-27; column 4, lines 42-65; column 5, line 62-column 7, line 14; claims 1-3).

- Document D3, cited by the applicant, describes a cosmetic composition comprising salicylic acid or a salt thereof and a gelling agent in the form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof (Cf. D3, page 2, line 25-page 4, line 14; page 7, line 3-line 26; page 10, line 3-line 26; claims 1-9).

- Document D4, cited by the applicant, describes an antimicrobial composition comprising salicylic acid, ethanol, $FeCl_3$, Aristoflex AVC and Xantham Gum (Cf. D4, example 3; claim 1).

- None of the cited documents refers to cosmetically acceptable skincare composition in the form of a hydroalcoholic gel dispersion.

3. Inventive Step (Article 33(1),(3) PCT)

- The subject-matter of present claims 1-48 is considered as being inventive for the following reasons (Article 33(1),(3) PCT):

- The problem to be solved by the present application is to provide a skin care composition effective in the treatment of acne vulgaris.

- The solution proposed in the present application is a skin care composition suitable for topical application to the skin in the form of a hydroalcoholic gel dispersion, the composition comprising salicylic acid or a salt thereof and a gelling agent as described in present claim 1.

- Document D1, cited by the applicant, which is considered as the closest prior art, describes a cosmetic composition comprising salicylic acid or a salt thereof and a gelling agent in the

form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof.

- The difference between the teaching of the closest prior art and the subject-matter of present claims 1-48 is a form of a hydroalcoholic gel dispersion.

- Starting from D1, the person skilled of the art had no incentive to come to the claimed solution and therefore, the subject-matter of present claims 1-48 is considered as inventive according to Article 33 (1),(3) PCT.

- Claims 40-44 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

4. Industrial Application (Article 33(4) PCT)

- The subject-matter of present claims 40-44 is considered to be industrially applicable; claims 40-44 therefore, satisfy the criterion set forth in Article 33(4) PCT.

43. A method as claimed in Claim 40, which method is a cosmetic method.

44. A method as claimed in any one of Claims 40 to 43, wherein the composition is a composition as claimed in any one of Claims 2 to 39.

45. The use of a copolymer of acryloyl dimethyl tauric acid or a salt thereof as a gelling agent in a cosmetically acceptable skincare composition comprising a hydroalcoholic gel comprising salicylic acid or a salt thereof, provided that if the composition contains xanthan gum, then it does not contain iron trichloride.

46. An article comprising a fibrous substrate impregnated with a cosmetically acceptable skincare composition in the form of a hydroalcoholic gel dispersion, the composition comprising salicylic acid or a salt thereof and a gelling agent in the form of a copolymer of acryloyl dimethyl tauric acid or a salt thereof provided that if the composition contains xanthan gum, then it does not contain iron trichloride.

47. An article as claimed in claim 46, wherein the fibrous substrate is impregnated with the skincare composition in an amount in the range from 10 to 30% by weight, preferably from 15 to 25% by weight and most preferably from 18 to 22% by weight of the fibrous substrate.

48. An article as claimed in either one of claims 46 or 47 wherein the substrate comprises cellulose or cotton fibres or a mixture thereof.